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Attached are the joint comments of the Air Transport Association and the Regional Airline Association on the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. Please do not hesitate to contact me if you have any difficulty opening this document.

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**BEFORE THE**
**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION**

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| In re: | ) | |
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| | ) | Docket HHS-04-7984 |
| Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs | ) | |
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The Air Transport Association of America, Inc. ("ATA")[1] and the Regional Airline Association ("RAA")[2] submit these comments on the Department of Health and Human Services' ("HHS") proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs, in response to the notice published in the Federal Register on April 13, 2004 ("Notice"). Although ATA's and RAA's member airlines are not directly covered by the Mandatory Guidelines, they are subject to Department of Transportation ("DOT") regulations which by statute must incorporate these scientific and technical guidelines and any amendments to them. As a result, our members have a real and substantial interest in any changes to the Mandatory Guidelines that might in turn necessitate a change in DOT's drug testing program for the transportation industry. While we recognize that the proposed revisions afford a certain amount of discretion to each agency to determine how to tailor its own drug testing program, we appreciate the opportunity to provide comments at this time in order to identify two areas of general concern: alternative specimen tests and additional testing options.

[1] ATA serves as the principal trade and service organization of the major scheduled air carriers in the United States. ATA's members include: ABX Air, Alaska Airlines, Aloha Airlines, America West Airlines, American Airlines, ASTAR Air Cargo, ATA Airlines, Atlas Air, Continental Airlines, Delta Air Lines, Evergreen International Airlines, FedEx Corp., Hawaiian Airlines, JetBlue Airways, Menlo Worldwide Forwarding, Midwest Airlines, Northwest Airlines, Polar Air Cargo, Southwest Airlines, United Airlines, UPS Airlines and US Airways; associate members include Aeromexico, Air Canada, Air Jamaica and Mexicana.

[2] RAA's members are: Aerolitoral, Air Canada Jazz, Air Serv International, Air Wisconsin Airlines Corporation, AirNet Systems, Allegheny Airlines, American Eagle Airlines, Atlantic Southeast Airlines, Big Sky Airlines, Cape Air, Chautauqua Airlines, Chicago Express Airlines, Colgan Air, Comair, CommutAir, Corporate Air, Corporate Airlines, Delta Connection Inc., Eagle Aviation, Empire Airlines, Era Aviation, Executive Airlines, ExpressJet, FedEx, Flight Options, Flyin'HI, Grand Canyon Airlines, Great Lakes Aviation, Gulfstream International Airlines, Horizon Air, IBC Airways, Independence Air, Island Air, Mesa Airlines, Mesaba Aviation, MidAtlantic Airways, New England Airlines, Pace Airlines, Pinnacle Airlines, PSA Airlines, Piedmont Airlines, Republic Airlines, Salmon Air, San Antonio Airlines, Seaborne Airlines, Shuttle America, SkyWest Airlines, Skyway Airlines, Trans States Airlines, and US Airways Express.

Alternative Specimens

Our primary concern is with the expansion of the Mandatory Guidelines to include testing of hair, sweat and oral fluid specimens. We share HHS' desire to identify and develop reliable alternatives or complements to urine testing, particularly in light of the increasingly sophisticated methods available to suborn urine testing through adulteration, dilution or substitution of specimens. However, we believe that the proposed standards and procedures for alternative specimens are premature and inadequately supported by peer-reviewed scientific evidence and real-world experience at this time, at least as reflected in the Notice.

The incompleteness of the record before HHS is evidenced by the requests in the Notice for additional information on the use of alternative specimens. For instance, HHS asks "whether commenters are aware of any other studies or data that would cast more light on the appropriateness of using any of the alternative specimens or on limitations on how the specimens should be used." 69 Fed. Reg. 19675. Similarly, the Notice explains that while HHS proposes to use the same analytical and quality control requirements for validity testing of alternative specimens that have been established for urinalysis, "information may become available during the public comment period to suggest that the requirements for each type of specimen should be different." 69 Fed. Reg. 19684. While an agency's request for public comments often elicits additional data that may help to support, refine or refute a proposal, the notice and comments process should not be used to gather essential information that should have been before the agency in developing the proposal. Instead of publishing a proposed revision of the Mandatory Guidelines including alternative specimens, it would have been more appropriate to issue another working draft with a request for supplemental information and informal comments, as has been done by the Drug Testing Advisory Board in the past.

The insufficiency of data available to HHS is further evidenced by the references to suspected or known limitations in the studies relied on to develop these guidelines. For example, the discussion of hair testing notes that animal studies have shown that hair color plays a role in the concentration levels of various drugs, and that a limited number of human clinical controlled studies indicate similar results. However, other studies cited in the Notice failed to detect a significant hair color effect. Despite the inconclusive results and limited number of studies, HHS "still proposes to go forward with incorporation of this new technology." 69 Fed. Reg.19676.

Similar data gaps exist for the other alternative specimens. With respect to oral fluids, HHS notes that further scientific study is needed to be able to differentiate between an individual who has used marijuana and someone who was merely present in a room in which it was being used by others, and in discussing sweat tests HHS states candidly that "[t]he incorporation of drugs into sweat is poorly understood." 69 Fed. Reg.19676. Although all of these testing methods offer some promise of viable alternatives to urinalysis and deserve further study, the current state of knowledge about them is insufficient to support Federal standards for their use in mandatory drug testing programs.

The Notice identifies three "serious" concerns with laboratory capabilities identified during its performance testing pilot program. The first is an indication of the relative immaturity of these procedures: not all participating laboratories had developed the capability to test for all required drug classes or to perform the tests with acceptable accuracy. While this shortcoming also concerns ATA and RAA, it is one that may be cured by time and experience. The second and third concerns – that some drug classes are more difficult to detect than others, and that it varies by the type of specimen – may be more difficult to overcome.

Although HHS suggests that "special awareness" would be required in selecting the type of test to use when use of a specific drug is suspected, this does not address the more common situation in random or pre-employment testing, when use of a particular drug is not suspected but cannot be ruled out. Furthermore, it would require drug testing program managers to make a judgment about which type of test would be best for a given situation, since HHS proposes prohibiting collection of more than one type of specimen from the same donor at the same time (with the exception of oral fluid specimens, as discussed below). Nowhere in the proposed revisions is guidance provided on how this determination should be made.

The most glaring deficiency in the proposed alternative specimens is in oral fluid specimens. As described in the Notice, only the parent drug of marijuana (THC) can be detected in oral fluid specimens, and as noted previously it is currently impossible to tell whether it is present due to drug use by the individual or as a result of environmental contamination. HHS' suggested solution – collecting a urine specimen at the same time as the oral fluid specimen – would negate the advantages of using an oral fluid specimen as described in the Notice (collection more easily observed and less invasive than urine specimens). Our members' experience with the DOT saliva test for alcohol, which must be followed by a breath test if positive, suggests that the requirement for a second test would make oral fluid specimens a less-than-useful method of meeting drug testing program requirements.

HHS proposes limiting use of alternative specimens to certain situations and for specified reasons. ATA and RAA support the concept of targeting the use of alternative specimens to those situations in which the detection window of a specimen type is especially well-suited to the purpose of the test, but more should be known about the advantages and disadvantages of each before they are assigned to specific purposes within the workplace drug testing program. Although the rationale given by HHS for limiting the use of each proposed alternative specimen seems reasonable, it does not make the case for their superiority over urine specimens.

For instance, limiting the use of oral fluid specimens to reasonable suspicion/cause and post-accident testing because of the extremely short period of detection (less than one to approximately 24 hours) makes intuitive sense, but the current test's inability to detect marijuana use severely limits its usefulness in these situations. In the same vein, prohibiting the use of hair specimens for reasonable suspicion/cause and

post-accident testing appears reasonable since drug use within the past 7-10 days would not be detected, and hair specimens may not be suitable for return-to-duty and follow-up testing, depending on the last known drug use, since drugs or drug metabolites will be detected for 90 days or longer in hair. However, whether or not hair specimens are suitable and sufficient for pre-employment and random testing would depend on whether questions about the effect of hair color on drug concentrations can be satisfactorily addressed. ATA and RAA agree with HHS that sweat specimens, which currently are limited to sweat patches, are not useful for pre-employment, random, reasonable suspicion/cause and post-accident testing since the patch only detects drugs used shortly before and during its application. It is less obvious that sweat tests are well-suited for return to duty and follow-up testing as HHS contends, 69 Fed. Reg.19677, particularly given questions about skin sensitivity, environmental contamination and pre-application cleaning procedures. The use of sweat testing for monitoring drug use in the criminal justice system and during substance abuse treatment in the private sector does not establish its usefulness in the workplace environment.

Although we recognize and share HHS' concerns regarding adulteration, dilution and substitution of urine samples, we take issue with the statement that "urine drug testing may be least suited for pre-employment." 69 Fed. Reg. 19679. Despite the opportunity for individuals to suborn pre-employment urine testing (or to avoid a positive result by refraining from drug use for a period of time prior to being tested) our members have found it to be remarkably effective at screening out prospective employees with drug abuse problems. The collection and testing of urine specimens is well-established, and familiarity of drug testing program managers and collectors with the procedures and range of results helps to thwart would-be suborners. Introducing alternative specimens for pre-employment testing would add a level of uncertainty into the process, at least at this point when the accuracy and reliability of some of these tests remains in question. Moreover, most airlines have provisions for urine testing procedures in their contracts with unions representing employees covered by DOT's drug testing program. The mere existence of HHS-approved alternative tests would create pressure on airlines to make them available to their employees, even if they were deemed less reliable than urine tests or otherwise unsuitable for the situation.

Training, certification and availability of collectors and laboratories to conduct drug testing continues to be an issue for airlines and other transportation sector employers subject indirectly to HHS guidelines. Expanding the Mandatory Guidelines to include three alternative specimens, none of which is well-established as a scientific or technical matter, would only serve to exacerbate this problem. It would be necessary to identify not only HHS-certified companies, but to differentiate among them based on which tests they are certified to perform. This is likely to increase the cost, or at least the complexity, of managing a DOT drug testing program. Furthermore, unless and until the accuracy of these tests and the achievability and sustainability of this level of accuracy can be better established, airlines will be in the untenable position of having employees question test results that could have career-ending consequences. HHS acknowledges that the results from four rounds of performance testing only demonstrated that "*some* laboratories testing alternative specimens have been able to achieve performance levels *approaching*

those levels applied to urine testing laboratories." 69 Fed. Reg. 19674 (emphasis added). This simply is not good enough when so much is at stake. HHS "remains committed to . . . identifying and using the most accurate, reliable drug testing technology available." 69 Fed. Reg. 19674. Until further scientific research is conducted and the results fully vetted through an objective process, only urinalysis meets these criteria.

2. Additional Types of Testing Locations and Methods

ATA and RAA support the concept of expanding the number of facilities certified by HHS to perform drug testing. However, although HHS describes the proposed Instrumented Initial Test Facilities ("IITF) as having the potential to more quickly and economically meet special local testing needs, 69 Fed. Reg. 19677, it is unclear whether making this option available will significantly improve accessibility or lower the cost of laboratory testing. HHS acknowledges that "[w]ith the rigorous certification, performance testing, and inspection requirements proposed for the IITF, it is unlikely that the total number of laboratory and laboratory "like" facilities [including IITFs] will increase very much." Furthermore, as proposed each IITF, as well as each full laboratory, would have to obtain a separate certification for each type of specimen because the procedures are different for each. This would likely further limit, rather than expand the availability of certified laboratories.

The availability of point-of-collection tests ("POCTs") for drugs in urine could be helpful in many situations in which quick results and flexible test locations are desirable. Assuming that an acceptable accuracy level can be achieved and maintained, particularly in terms of negative results (since positive result would require confirmatory testing), we see no reason why POCTs would not be suitable for all testing situations. If, on the other hand, HHS' statement that POCT of urine are least suited for pre-employment, return to duty and follow-up testing is based on concerns about accuracy, then we question their suitability for any situation.

Of course, even if the accuracy and reliability of the device were certified by HHS, DOT would have to promulgate procedures and standards for their use in the transportation industry. Although we have some concerns about the ability of specimen collectors in the field to accurately read and interpret test results, ATA and RAA reserve more specific comments about the use of POCTs until such a time as DOT opts to do so. Due to the concerns expressed above about oral fluids testing in general, ATA and RAA would not support the use of POCTs for oral fluids at this time.

In conclusion, ATA and RAA have some general concerns about the level of scientific evidence and practical experience underlying the proposed revisions to the Mandatory Guidelines, particularly in the two areas discussed above. We urge HHS to defer revising the guidelines to include alternative specimens until additional studies have been conducted and/or identified and the results of those studies reviewed and analyzed by the scientific community as well as by affected industries. This could be accomplished through an additional round of review by the Drug Testing Advisory

Board, or might be referred to the National Research Council or similar body to develop a more comprehensive review of the literature. In addition, although the development of POCTs for urine is further evolved than tests of alternative specimens, we recommend that HHS document the accuracy and reliability of available POCT devices before incorporating them into the Mandatory Guidelines.

Respectfully submitted,

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